

REMARKS

Status of the Claims

A Request for Continued Examination is being filed concurrently with the present response. Applicants' have requested that the Amendment filed December 30, 2010, be entered and that the arguments and amendments made be further considered by the Examiner.

After entry of the Amendment filed December 30, 2010, and the instant Amendment, claims 94-96 and 98-122 are pending in the above-identified application and stand ready for further action on the merits. Claims 94, 112, 115 and 116 are independent. Claims 96, 101 and 106-116 stand withdrawn from consideration as being drawn to non-elected inventions and species.

New claims 120-122 have been added and support for the new claims can at least be found at page 18, line 36 to page 19, line 15; page 22, line 27 to page 23, line1; page 37, line 29 to page 38, line 17; page 43, lines 16-31; page 44, lines 25-29; page 56, lines 1-24; original claims 81 and 84; and in the Examples of the present Specification. Reconsideration of this application, as amended, is respectfully requested.

Rejection Under 35 U.S.C. § 112, first paragraph (Enablement)

Claims 94, 95, 98-100, 102-105 and 117 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Applicants respectfully traverse.

At page 4 of the Advisory Action it is alleged that the Specification, while being enabling for making those glycoconjugates having a well-known utility, "does not reasonably provide enablement for the full scope of the glycoconjugates made by said method." It is further asserted that "[a]bsent a well-known, or specific and substantial utility, one of skill in the art would not know how to use the products made by the full scope of the instant method." Applicants respectfully disagree.

Applicants respectfully request that the Examiner reconsider the enablement arguments presented in the Amendment filed on December 30, 2009, in further view of the comments provided below.

Applicants respectfully point out that specific and substantial utilities associated with products (including mixtures) prepared by the claimed methods include the following:

1. Use for identifying products for quality control or marking of products

The specific utility of the glycoconjugates produced by the claimed methods is based in a) the glycoconjugates having a specific mass spectrometric profile and b) there being a greater number of isomeric structures in the glycoconjugates prepared by the claimed methods than are found in other known carbohydrate mixtures. These properties make analysis of the material difficult, and production of fakes or copies of the product glycoconjugates is hindered without knowledge of the exact production conditions and raw materials used in their making.

The previously cited art, Kanie et al., "Solid Support Oligosaccharide Synthesis and Combinatorial Carbohydrate Libraries", 2001, pp. 239-256, merely discloses saccharides where monosaccharide A is bound to saccharide B to form A-B, while the claimed invention produces glycoconjugates including A-B, B-A, A-A and B-A with both α - and β -anomeric linkages for disaccharides and a much larger variation for trisaccharides. One of ordinary skill in the art would recognize that the number of isomers involved would quickly make the regular isolation of individual components and analysis of the individual species in the product of the claimed methods very difficult.

Thus, the isomeric complexity of the glycoconjugates produced by the claimed methods provides a chemical code that is not unlike the complexity of the computer code for an encrypted computer file. The specific utility of the products of the claimed method includes that they cannot be copied without knowledge of the "coding"/synthesis conditions, because their analysis would be very challenging. Even knowing the chemical make-up of each component, a person intent on copying the glycoconjugate products of the claimed methods would need to synthesize each component separately, because the actual synthesis conditions used in their production could not be readily determined. This copying process would be very expensive.

In principle, the claimed methods are analogous to a computer that produces novel encrypted and unbreakable files. There is no need to ascertain the specific utility of each protected file as the utility lies within their general and specific and substantial property of being encrypted.

2. Well-known utility as novel foods

At pages 8 and 9 of the final Office Action issued June 24, 2009, it was alleged that the glycoconjugates prepared by the claimed methods might not be safe or GRAS, based on

examples of molecules which are dangerous when injected. Applicants previously argued that practically any food is dangerous when injected. In contrast, oligo- and polysaccharides are generally non-absorbable and thus do not involve a risk of harmful effects. Applicants would like to further point out that the novel linkages present in the products prepared by the claimed methods make the structures practically non-biodegradable in the human gastrointestinal tract. Rather the products prepared by the claimed methods can function as low carbohydrate fiber, just as polydextrose products do (*e.g.*, by Danisco).

3. Use of novel polysaccharides or oligosaccharides in a molecular library

One of ordinary skill in the art would recognize that novel oligosaccharides or polysaccharides prepared by claimed methods could be used as components of a carbohydrate library. Such a library could be used in any number of ways. This is supported, for example, by a review of the carbohydrate content of current glycan arrays available at the Scripps Institute (Consortium for Functional Glycomics, <http://www.functionalglycomics.org/static/consortium/organization/sciCores/coreCtoH.shtml>) and the London Imperial College (<http://www.genomeweb.com/arrays/ten-feizi-imperial-college-medicine-glycoarrays>). Such institutions collect practically any and all carbohydrate materials available, because collected isomeric structures collected might be useful in screening for biological activity. The claimed methods can provide a library having isomeric diversity (see point 1, above). The glycoconjugates prepared by the claimed methods are especially useful for screening of carbohydrate binding proteins such as lectins, antibodies or enzymes.

Monosaccharides used in the claimed methods can be either natural monosaccharides or isomers thereof and may further comprise other specific natural products of well-known utility. Furthermore, a natural monosaccharide can be identified as being at least a partial epitope that is recognized by a carbohydrate binding protein, when isomers of the monosaccharide are found at un-bound and at recognition sites of the protein. Therefore, there is utility in having a carbohydrate mixture that comprises both natural monosaccharide residues and isomers thereof.

The well-known utilities of the products of the claimed invention are further emphasized in mixtures comprising natural oligosaccharide or polysaccharide products. The claimed invention can be used to produce common natural oligosaccharides and analogs thereof, such as

galactooligosaccharides (homotypic oligosaccharides as parts of mixed compositions, *e.g.* claim 119), mannooligosaccharides, and poly-N-acetyllactosamines, as well.

There are many more specific and well-known uses for carbohydrate mixtures comprising a natural monosaccharide isomer, such as for a library comprising a natural monosaccharide residue, for a library comprising a specific natural glycan product, and for a mixture comprising natural carbohydrate products.

Applicants respectfully point out that claim 95 specifically defines natural monosaccharide structures of groups B-F. Hexoses used in the claimed methods can be common natural hexoses such as mannose, galactose or glucose or their simple epimers, and a pentose used in the claimed methods can be natural xylose or its epimer (*e.g.*, useful for analysis of xylose epitope binding). Therefore, the products of such claimed methods comprise known natural carbohydrates with at least homotypic oligosaccharides of at least one natural monosaccharide type with well-known utility. (See new claim 120.)

As the claimed invention provides new synthesis methods producing a broad scope of products, a vast number of molecules can be produced by the claimed methods just as with any other chemical synthesis method.

In view of the discussion above, Applicants respectfully request that the rejection of claims 94, 95, 98-100, 102-105 and 117 under 35 U.S.C. § 112, first paragraph, be withdrawn.

CONCLUSION


All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Stephanie A. Wardwell, Ph.D., Registration No. 48,025 at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

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Respectfully submitted,

By 

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